K014148 (P.1 of 2)

510(k) SUMMARY (per 21 CFR 807.92 (c))

1. SUBMITTER

JAN 17 2002

Walter Lorenz Surgical, Inc.*
1520 Tradeport Drive
Jacksonville, FL 32218
FDA Registration No. 1032347

*Walter Lorenz Surgical, Inc. is a wholly owned subsidiary of:
Biomet, Inc.
Airport Industrial Park
Warsaw, Indiana 46580
FDA Registration Number: 1825034

2. PRODUCT NAME

Common/Usual Name: Radiographic Marker

Proprietary Name: Self-Drilling Radiographic Marker

3. DEVICE CLASSIFICATION

The FDA has cleared radiographic markers via 510(k) Premarket Notifications as Product Code NEU Marker, Radiographic, Implantable – Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for implantable radiographic markers.

4. PREDICATE DEVICE

The predicate device is the Tantalum Bead – Radiographic Marker cleared under Biomet 510(k) number K010348 on May 3, 2001.

5. DESCRIPTION OF THE DEVICE

Self-Drilling Radiographic Markers are stainless steel bone screws used as radiographic markers, and may be implanted into bone during orthopedic or other surgical procedures. These devices are used to measure movement of implants after surgery with the aid of an X-ray. Self-Drilling Radiographic Markers are applied with manual surgical instruments.

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6. INTENDED USE OF THE DEVICE

The Self-Drilling Radiographic Markers are stainless steel screws indicated for use as radiographic markers and may be implanted into bone during orthopedic or other surgical procedures. These devices are used to measure movement of implants or serve as a reference point to locate anatomical structures with the aid of an X-ray.

7. STATEMENT OF COMPARISON OF TECHNOLOGICAL FEATURES

Both the new and predicate devices consist of non absorbable material (stainless steel, tantalum) listed in the FDA's Biomaterials Compendium and list of FDA recognized standards. Both the predicate devices and the modified self-drilling devices are implanted into bone during surgical procedures to radiographically mark a surgical location (e.g. implant, prosthesis, or anatomic position). The metallic materials and intended use as radiographic markers are technically equivalent. The modified device is being added to resolve differences in surgeon preference.

8. CONCLUSIONS

The use of modified stainless steel screws and the predicate tantalum beads as radiographic markers is substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 7 2002

Ms. Kim Reed
Regulatory Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K014148
Trade/Device Name: Self-Drilling Radiographic Markers
Regulation Number: 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: December 17, 2001
Received: December 18, 2001

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K014148

Device Name: Self-Drilling Radiographic Markers

Indications for Use:

Self-Drilling Radiographic Markers are used as radiopaque markers and may be implanted into bone during orthopedic or other surgical procedures These devices are used to measure movement of implants or serve as a reference point to locate anatomical structures with the aid of an X-ray.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, [illegible]ative
and Neurological De[illegible]

510(k) Number K014148

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